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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,402	01/13/2006	Koji Ukai	0425-1242PUS1	9872

2292 7590 08/30/2007

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
HUANG, GIGI GEORGIANA	
ART UNIT	**PAPER NUMBER**
1618	

NOTIFICATION DATE	DELIVERY MODE
08/30/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/564,402	UKAI ET AL.	
	Examiner	Art Unit	
	GiGi Huang	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Non-Final Rejection

1. Claims 1-8 are present for examination at this time.

Information Disclosure Statement

2. The information disclosure statement filed January 13, 2006 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because there is no translation of JP 11-501950 in full or abstract form. The reference has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 5 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is drawn to placebo granules containing "no pharmaceutically active substance". This is indefinite as most materials utilized in

compositions have some degree or level of activity and dependent on the amount of material utilized, can play several different roles in a composition. A clear example is citric acid, which is an acid capable of varying level of activity. It is commonly used as a buffer, an antioxidant, and as a main constituent of a formulation. It can be viewed as an active ingredient, an excipient, and fragrance (additive). The same can be applied to bases. They are commonly used as buffers and antacids. An additional example is alginate. It is a stabilizing agent, tablet binder, disintegrant, used in the treatment of heartburn, and a thickener. The term is unclear as to provide for one skilled in the art to know what the metes and bounds of the invention would be.

5. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a recitation of intended use and attempted to further limit the dependent claim by reciting properties, specifically viscosity, of a different product than the one claimed. The other product is the suspension of the dispersed preparation being claimed which has not yet been formed and it to be formed in the future. While one of skill in the art can modify the amount of thickeners or water present for dispersion, as there is no amount of water given, the product claimed is the preparation, not the future suspension. It is unclear how the intended use and viscosity of a second product limitation defines the metes and bounds of the invention. This has not been given any patentable weight.

6. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. The claims are drawn to a preparation "capable of being administered through an NG tube by dispersing in water before administration". This is a recitation of intended use, which does not have patentable weight in a product claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5, 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Depui et al. (WO 97/25066).

Depui et al. teaches a pharmaceutical dosage form comprising proton pump inhibitors, bases (antacid agents), alginates, thickeners, polymers (including enteric polymers), and other pharmaceutical excipients to form multilayered tablets, sachets, and multiple unit tableted dosage forms. The proton pump inhibitors may be utilized in neutral or salt forms, including racemic form or pure form. The specific proton pump inhibitors taught are omeprazole (and encompassing its optical isomer esomeprazole), lansoprazole, pantoprazole, and pariprazole (rabeprazole). The proton pump inhibitors are in granular form, individually enterically coated with a polymer (including hydroxpropyl methylcellulose), combined with alginate/antacid agent powders or granules and other excipients to be compressed into a tablet. The multiple unit dosage

form is also taught to be dispersed in liquid and can be given to patients with swallowing disorders. The formulated core material is in a granules size approximately between 0.1 and 4mm and preferably between 0.1 and 2mm.

The placebo granules can be any number of materials in the tablet including the bases (antacids), the alginate, the microcellulose, buffers, lubricants, or any other number of excipients as they are all granules, even in molecular form. Example 3 (Page 27-28) is one of several examples, fulfilling the claims. Depui teaches the prepared active pellets/granules comprising omeprazole, hydroxypropyl methylcellulose and Polysorbate 80, and the tablet comprising those active granules with calcium carbonate (base), magnesium hydroxide (base), potato starch (glidant, diluent, disintegrant and binder), water, microcrystalline cellulose, crosslinked polyvidone (polyvinylpyrrolidone) (Abstract, Page 2, lines 5-10, Page 3, lines 10-18, Page 4, lines 15-21, Page 5, lines 15-30, Page 6, lines 1-29, Page 7, lines 1-20, Page 8, lines 20-25, Page 9, lines 1-10, Page 10 (all), Page 11, lines 10-15, Page 12, lines 12-30, Page 13, lines 1-2, 25-30, Page 14, lines 9-25, Page 16, lines 1-8, Page 22, lines 14-15, Example 1, Page 23 (all), Page 25-26, Example 2, Page 27-28, Example 3, Page 29, Example 4, Claim 1-8, 13-15, 17-18, 20-23).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

9. Claims 1-5, 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Ukai et al. (U.S. Pat. Pub. No. 2002/0039597).

Ukai et al. teaches a composition comprising benzimiadzole type compounds and its alkali salts-all are proton pump inhibitors, bases, thickeners, polymers (including enteric polymers), and other pharmaceutical excipients that are formed into tablets soluble or rapidly degradable (dispersible) in water or in gastric acid. The specific proton pump inhibitors taught are omeprazole (and encompassing its optical isomer esomeprazole), lansoprazole, pantoprazole, and rabeprazole. The proton pump inhibitors are in granular form, individually enterically coated with a polymer (including hydroxypropyl methylcellulose), combined with bases, crospovidone, granules not containing the proton inhibitors ("placebo"), and other excipients to be compressed into a tablet. The formulated core material is made, granulated, dried, and screened through a 24-mesh screen, producing particle sizes of about 841 micron or less (see STG Particle Size/Screen Mesh Comparison).

Tables 6-13 (Pages 6 -8) and Examples 28-29 provide several examples, fulfilling the claims. Ukai teaches the prepared active granules comprising sodium rabeprazole, carbonate, mannitol, and hydroxypropyl cellulose. The granule without the proton inhibitor has mannitol and hydroxypropyl cellulose (also a thickener) with variation. Crospovidone is also added with other excipients and the tablet is formed (Abstract, Paragraph 2, 4, 7, 9-14, 17, 20-21, 25-26, 30-3, 40-43, 72-82, Claims 1-15).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Double Patenting

10. Claims 7 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-18 and 22 of copending Application No. 10/938554. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Application No. 10/938554 are to the specific proton pump inhibitor rabeprazole which is included in the short Markush group in instant claim 8 and anticipates the genus of proton pump inhibitors in instant claim 7, as a species can anticipate a genus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. Claims 1-8 are rejected.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Depui et al. (U.S. Pat. No. 6132771), Robinson et al. U.S. Pat. Pub. No. 2002/0160046 or U.S.Pat.No.6749867), Hall et al. (U.S.Pat.Pub.No.2006/0204585)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER